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13 August 1998 John H. Sadler, M.D.

Comments on FDA/CDRH questions regarding FDAMA adjustments and goals.

As a longtime consultant and former Chair of the GI-GU Device Panel, I am familiar with some of the operations and a number of the people at CDRH/ODE. As Co-Chair of AAMI's Renal Disease & Detoxification Committee, I participate in writing standards and practice guidelines for clinicians and manufacturers. That role extends to ISO committee work, and raises awareness of the need for harmonization of standards to promote quality consistently and avoid extra expense and duplication of effort. At the same time, standards must have specifics and limits accompanying their principles, or any standard is meaningless. Although there is obligatory tension among these participants in the process of product approval, distribution, and monitoring, there are many common purposes. It is critical that the parties treat each other with respect and attempt to achieve reasonable consensus.

The questions posed by FDA are appropriate and helpful in focusing the discussion. Each represents a goal to be sought. Many grew out of problems that are due to the lack of adequate numbers of FDA staff and the lack of direct, open communication between parties. The latter issue is decreasing as the Agency holds more meetings and is more accessible to the user community, scientists, and producers. The shortage of highly competent people is not unique to FDA, and will not be solved easily. Many competent scientists do not find a government career appealing. There is likely to be a perpetual need for knowledge and skills that are not available within the Agency.

Because of that need, the requirement for effective outside consultation is absolute. New mechanisms to develop teams to carry out studies and evaluations under FDA oversight appears to be most desrable. Since such teams would only work when there is a need for their services, their cost would be less than fulltime staff, and individuals who are not willing to become employees full time may be ready to serve part time in roles they find interesting.

* My first recommendation is, develop more outside sources to add capabilities and effectiveness for specific tasks. (Addressing question 4 specifically, 6 approximately, and all generally.)

The repeated expression of a desire to improve and clarify communication with producers, users, and the public is commendable - and acknowledges prior shortcomings. The simple answer is, listen. Listen to those you serve and those you regulate with openly expressed goals in view, and refine the message together. It is not necessary to control every step of the process and every statement made, since FDA has final authority over any document it uses. Let the consumers and the producers and the users help express the message in language they can accept and use, and you can avoid much of the "federalese" that does not reflect well on the Agency or carry out its communications effectively. If these groups know that they are taken seriously and can make a difference, you will get good participation and a better message to use.

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* My second recommendation is, continue on your path to open up and collaborate with the communities you serve, allowing them to contribute to the communication of your purpose. (Addressing questions 1 & 2 and affecting all.)

The problem of surveillance is not amenable to old practices. The Agency staff will not be permitted to grow as the potential for surveying grows. Different means are necessary to achieve the information that will give reasonable assurance of low, acceptable risk. Safety sounds absolute, and can never be absolute. Low risk can be defined precisely, and thus success or failure also recognized objectively. Initial surveillance of manufacturers will always be essential, but subsequently, data on operations and review of outcomes of using the product assures that the goals are met. Test in detail at first, then keep results in view. Manufacturers can help with this if they can have assurance of fairness and relief from more troublesome measures to monitor product safety.

* My third recommendation is, be innovative in monitoring outcomes and know enough to have confidence that outcomes are the final evidence of quality. Details of processes can be supplied by manufacturers. (Addressing Question 3.)

I regret that I cannot make my comments in person. Most of all, this is a plea for reasonable people to work together from different perspectives to reach common goals with reasonable effort. Doing this should let each party bear no more than its fair share of the cost and effort of demonstrating safety and effectiveness to an acceptable degree. It will not achieve perfection, but can accomplish steady improvement.

I am available to expand upon any of this. Please keep in touch.

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